The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

Paper No. 19

#### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NOLA J. MC VICKER

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Application No. 08/173,376

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ON BRIEF

SMITH and ROBINSON Administrative Pat

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, <u>Administrative Patent Judges</u>. ROBINSON, <u>Administrative Patent Judge</u>.

#### **DECISION ON APPEAL**

This is a decision on the appeal under 35 U.S.C. ' 134 from the examiner's final rejection of claims 6 and 7, which are all of the claims pending in the application.

Claim 6 is illustrative of the subject matter on appeal and reads as follows:

6. A method for preventing insects from biting a vertebrate species, said method consisting essentially of the steps of topically applying a pesticide composition to a surface of said vertebrate species, said composition consisting essentially of about 0.25 percent to about 10 percent by volume of a water swellable polycarboxylated homopolymer or copolymer and an effective amount of a pesticide in a volatile non-aqueous solvent,

drying the applied pesticide composition to form a surface adherent non-aqueous film of the polymer and pesticide on the vertebrate surface, and

thereafter contacting the dried film with water to swell the film and promote release of the pesticide from the surface adherent film.

The references relied upon by the examiner are:

Chromecek 3,966,902 June 29, 1976 Amidon et al. (Amidon) 5,221,698 June 22, 1993

## **Grounds of Rejection**

Claims 6 - 7 stand rejected under 35 U.S.C. ' 112, first paragraph, as being based on a non-enabling disclosure.

Claims 6 - 7 stand rejected under 35 U.S.C. ' 103. As evidence of obviousness, the examiner relies upon Chromecek and Amidon.

We reverse both rejections.

## **Discussion**

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims and to the respective positions articulated by the appellant and the examiner. We make reference to the Examiner's Answer of February 16, 1996 (Paper No. 14) for the examiner's reasoning in support of the rejections and to the appellant's Appeal Brief of October 25, 1995 (Paper No. 13) and Reply Brief of April 22, 1996 (Paper No. 15) for the appellant's arguments thereagainst.

the examiner states (id.):

#### **Claim Interpretation**

Claim 6 is directed to a method for preventing insects from biting a vertebrate species by topically applying the defined pesticide composition to a surface of the vertebrate, drying the applied composition to form a surface adherent non-aqueous film on the surface of the vertebrate and, thereafter, contacting the dried film with water to swell the film and promote the release of the pesticide from the film. While the claim does not specify how the Adrying step is to be accomplished, we read the claim to require a positive drying step; whether it is accomplished by direct action designed to remove the non-aqueous solvent from the composition or whether the solvent is merely permitted to evaporate.

The rejection under 35 U.S.C. ' 112, first paragraph

Claims 6 - 7 stand rejected under 35 U.S.C. ' 112, first paragraph,

as being based on a disclosure which is not enabling for the prevention of insect biting. The examiner urges that Ano support can be found in the disclosure for the contention that such a method actual prevents biting." (Answer, page 3). In explaining the basis for this rejection,

There is no support for the claimed prevention of biting. The composition is presented with [the] assumption of water contact as sweat, but no support can be found in the disclosure for the contention that such a method actually prevents biting. For one in the art to meet these requirements, more information is required - Pesticide, copolymer or homolog, insect species, hosts, adjuvants, and pesticide/adjuvant concentrations.

The Patent and Trademark Office (PTO) bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicant as to the scope of

enablement. Only when the PTO meets this burden, does the burden shift to applicant to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

Factors appropriate for determining whether undue experimentation is required to practice the claimed invention throughout its full scope are listed in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include:

- (1) the quantity of experimentation necessary,
- (2) the amount of direction or guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the relative skill of those in the art,
- (7) the predictability or unpredictability of the art, and
- (8) the breadth of the claims

We point out that the guidance provided by the specification is merely one of the factors considered in determining whether the disclosure provided by applicant in support of a claimed invention is sufficient to permit those skilled in the art to which the invention relates to practice the invention without undue experimentation. That some experimentation may be necessary, does not equate to undue experimentation. Further, it is well settled that patent applicant is not required to disclose every species encompassed by their claims, even in an

unpredictable art. In re Angstadt, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976).

A conclusion of lack of enablement means that, based on the evidence regarding the above

factors, the specification, at the time the application was filed, would not have taught one

skilled in the art how to make and/or use the full scope of the claimed invention without undue

experimentation. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir.

1993).

On the record before us, we find that the examiner's statements, in support of this rejection, fall short of the requirement set forth above and, therefore, fail to reasonably

establish that one skilled in the art would doubt the disclosure provided in support of the

claimed method of preventing insect bites on vertebrates. The examiner's conclusory

statements relating to the Wands factors are not supported by facts or evidence which would

provide a reasonable basis for the conclusions reached. Thus, to the extent that we

understand the examiner's position in this rejection, the examiner has failed to make those

factual findings which must be made before a conclusion of "lack of enablement" may

properly be reached. Therefore, the rejection of claims 6 - 7 under 35 U.S.C. ' 112, first

paragraph, is reversed.

The rejection under 35 U.S.C. 103

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Claims 6 - 7 stand rejected under 35 U.S.C. ' 103 as being obvious over Chromecek and Amidon.

The examiner explains his reliance on Chromecek and Amidon stating (Answer, page 3):

Chromecek provides topical pesticide/insect repellants to prevent insect bites by applying films of polycarboxylated compounds with citronella (column 9, lines 45-48, column 2, lines 30-36, Examples 18, 22, 24 and 29). The method summarily is shown at column 8, lines 5-23; selected polymers with active agents are applied to skin in (column 7, lines 59-63) a suitable solvent. Further elucidation is seen in Amidon, column 7, showing application of a polymer to form a coating then, adding water, thus, the method steps of the claimed invention.

The examiner concludes that (id.):

[i]t would be obvious to one of ordinary skill in the insect protection arts to apply Chromecek's insect bite preventors, stepwise as shown by Amidon to coat a surface, skin, to protect a vertebrate, because Chromecek provides the composition, and Amidon provides similar compositions, and shows the application steps.

The initial burden of presenting a <u>prima facie</u> case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicants. <u>Id.</u> In order to meet that burden the examiner must provide a reason, based on the prior art, or knowledge generally available in the art as to why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. <u>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</u>, 776 F.2d 281, 297, n.24, 227 USPQ 657, 667, n.24 (Fed. Cir. 1985,. <u>cert. denied</u>, 475 U.S. 1017 (1986).

On the record before us, the evidence provided by the examiner in support of this rejection fails to support a conclusion that it would have been obvious to one of ordinary skill in this art to prevent insects from biting vertebrate species in the manner presently claimed. As we have interpreted claim 6, the method consists essentially of topically applying a pesticide composition to a surface of a vertebrate wherein the composition consists essentially of a water swellable polycarboxylated homopolymer or copolymer and an effective amount of a pesticide in a volatile non-aqueous solvent, drying the applied composition to form a surface adherent non-aqueous film of the polymer and pesticide on the vertebrae surface and then contacting the dried film with water to swell the film and promote the release of the pesticide from the film. Appellant acknowledges that Chromecek and Amidon (Brief, page 4):

teach the use of carboxylated polymers in carrier systems for bioactive agents. Chromecek describes carboxylated polymer carriers wherein the hydrophilic functional groups of the polymers are complexed to aluminum, zinc or zirconium. The Amidon et al. reference is directed to polymer compositions and a method of applying the compositions to a surface. Amidon—s method comprises the steps of applying a low viscosity hydrophilic

polymer/bioactive agent composition to a surface and adding water to form a gel coating.

However, as correctly pointed out by appellant (Brief, page 7):

There is simply no suggestion in the cited art to first dry an applied substantially nonaqueous composition, consisting essentially of a pesticide and a water soluble polymer, to form a film and subsequently contact the dried adherent film with water.

Amidon describes the application of a polymer to form a coating followed by adding water which causes a dramatic transition from a free-flowing fluid state into, most desirably, a viscoelastic gel. (Column 4, lines 26-29). Amidon does not contemplate the formation of a film or coating until water is added to the applied composition. This contrasts with appellants claimed method which calls for the drying of the composition to form a surface adherent non-aqueous film prior to the addition of water. Chromecek, while describing topical compositions which include similar polymers and bioactive ingredients, does not describe the application of the composition disclosed followed by a drying step and the subsequent addition of water.

Thus, in our opinion, the references relied upon by the examiner, whether considered separately or in combination, do not describe or reasonably suggest the presently claimed method of preventing insects from biting a vertebrate species. On the record before us, the evidence and reasoning provided by the examiner in support of the rejection of claims 6 and 7 under 35 U.S.C. ' 103 fall short of that which would reasonably support a <u>prima facie</u> case of obviousness within the meaning of 35 U.S.C. ' 103. Where

the examiner fails to establish a <u>prima facie</u> case, the rejection is improper and will be overturned. <u>In re Fine</u>, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, the rejection of claims 6 and 7 under 35 U.S.C. ' 103 over the combination of Chromecek and Amidon is reversed.

## **Summary**

The rejection of claims 6 and 7 under 35 U.S.C. ' 112, first paragraph is reversed.

The rejection of claims 6 and 7 under 35 U.S.C. ' 103 as unpatentable over Chromecek and Amidon is reversed.

# **REVERSED**

Sherman D. Winters ) Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) ) BOARD OF PATENT
	) ) APPEALS AND
	) ) INTERFERENCES
Douglas W. Robinson Administrative Patent Judge	) )

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